IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

CURDY et al Atty. Ref.: 2590-152

Appl. No. 10574003 (4067) TC/A.U. 1791

Filed: September 29, 2006 Examiner: Ninh V. Le

For: DEVICE AND METHOD FOR MAKING PARTICLES

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Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 18, 2010

APPEAL BRIEF and INTERVIEW SUMMARY STATEMENT

Appellant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the Examiner and requests an extension to file this Brief up to and including November 18, 2010 (the extension fee is being paid with this filing). With respect to the Interview Summary dated July 27, 2010, applicant agrees that it summarily sets forth the matters discussed, but disagrees that the claimed invention is not patentable.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

(I) REAL PARTY IN INTEREST

The real party in interest and assignee is DEBIO RECHERCHE PHARMACEUTIQUE S.A., which is a Swiss corporation.

(II) STATEMENT OF RELATED CASES

The appellant, the undersigned, and the assignee are not aware of any related appeals, interferences, or judicial proceedings (past or present), which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(III) STATUS OF CLAIMS

Claims 1-2, 4-7, 13 are pending in this application and are on appeal. All other claims have been cancelled without prejudice during prosecution.

(IV) STATUS OF AMENDMENTS

All amendments filed prior to the Final Office Action of March 23, 2010, have been entered. No amendments have been requested or entered after the Final Office Action.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is the only independent claim. The easiest way to summarize the claim is to parse it in the following manner, and the most convenient figures for the Board to view are Figures 3 and 7. Parenthetical reference numbers, as shown in the Figures, have been inserted into the claim to assist the Board.

Claim 1: A device for the continuous manufacture of microparticles or nanoparticles from at least one aqueous phase and one organic phase comprising (page 3, paras 1-4):

a homogenization compartment (page 3, para 4; page 4, para 2; Figure 3, #1) in the form of a cylinder (Figure 7) which is defined by a tubular wall forming the casing of said cylinder (Figure 7) and by a first side wall (Figure 3, #8) and a second side wall (Figure 3, wall [vertical line] opposite #8) which are positioned at each end of said tubular wall;

the device additionally comprising a first inlet (page 5, para 3; Figures 3 and 7, #2) and a second inlet (page 5, para 3; Figure 3, #3) which pass through said first side wall (Figure 3, #8) and which are appropriate for respectively delivering an organic phase and an aqueous phase to the homogenization compartment (Figure 3, #1) and an outlet (page 5, para 3; Figures 3 and 7, #5) appropriate for extracting a particle suspension from the homogenization compartment;

the homogenization compartment including a mixing system comprising a rotor (page 7, paras 5-6; Figure 7, #11) / stator (page 7, paras 5-6; Figure 7, #12) combination, wherein

a) said side walls (Figure 3, #8 and opposite wall of homogenization compartment #1) are positioned along a vertical plane,

b) the axis of symmetry of said cylinder is positioned horizontally (Figure 3),

c) the rotor (Figures 3 and 7, #11) is installed so that it rotates about a horizontal axis which passes through said second side wall,

d) said first inlet (Figures 3 and 7, #2) is a hollow tube positioned in the extension of the axis of the rotor and comprises a tip situated inside the rotor and inside the stator, and

e) the homogenization compartment (Figure 3, #1) exhibits a top side on which said outlet is situated (Figure 3, #5).

(VI) GROUNDS OF REJECTION TO BE REVIEWED

1. Are claims 1-2, 4-7, and 13 properly rejected under 35 U.S.C. 103(a) as allegedly being obvious over Muller (US Patent 5868973)?

The Examiner has withdrawn the specification objections on pages 2-4 of the Final Office Action of March 23, 2010. The official withdrawal of these objections is set forth in the last sentence on page 4 of Interview Summary of July 27, 2010.

(VII) ARGUMENT

Claims 1-2, 4-7, and 13 are pending in this application. The other claims have been cancelled without prejudice.

Claims 1-2, 4-7, and 13 Are Patentable Over Muller

On pages 5-10 of the Final Office Action, claims 1-2, 4-7, and 13 stand rejected as allegedly being obvious over Muller. The applicant requests the reversal of the rejection for at least the following reasons.

Turning to applicant's independent claim 1 (from which all claims directly or indirectly depend), Muller does not disclose or suggest the claimed device "for the continuous manufacture of microparticles or nanoparticles from at least one aqueuous phase and one organic phase" that requires the following critical claim features:

1. "a homogenization compartment in the form of a cylinder…wherein…said side walls are positioned along a **vertical** plane."
2. "homogenization compartment in the form of a cylinder…wherein…the axis of symmetry of said cylinder is positioned **horizontally**."
3. "the rotor is installed so that it rotates about a **horizontal** axis which passes through said second side wall."

4. "the homogenization compartment exhibits a **top side on which said outlet is situated**."

Applicant's Figures 3 and 7 are reproduced below and show the critical orientation of these claim features.

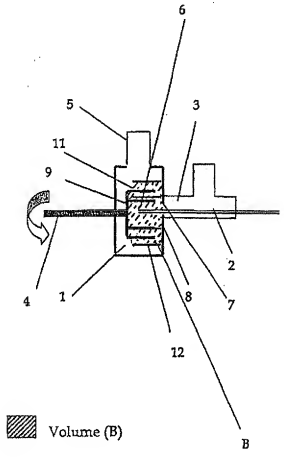


Figure 3.

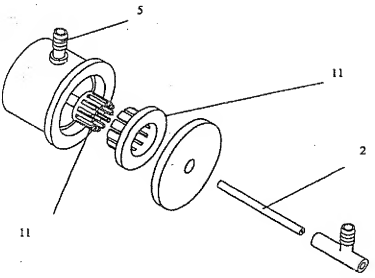


Figure 7

It is important to note that the applicants' claimed invention is specifically directed to "a device for the continuous manufacture of **microparticles or nanoparticles** from at least one aqueous phase and one organic phase." In contrast, Muller does not concern or even relate to the manufacture of microparticles or nanoparticles. Instead, Muller concerns a device that produces homogeneous **fibrets** from spinning horizontal nozzles, i.e., fibers having a very small diameter and a very high surface area per unit mass. See Muller at column 1, lines 9-10. Muller's fibrets are used for forming fiber networks or agglomerates such as in depth filters for liquid filtration or in webs for air filtration. See Muller at column 1, lines 24-40. Muller's device that uses a particular "star shaped" cluster of horizontal nozzles 46, 47, 48, 49 (column 9, line 50, and Figures 2-3)

and Muller's fibret technology are quite different than the claimed invention that concerns a device for the continuous manufacture of microparticles or nanoparticles.

Muller's device is depicted in Figures 2 and 3 below. Muller's Figures 2 and 3 show the **critical orientation** of Muller's features – which teach away from the applicant's claimed features.

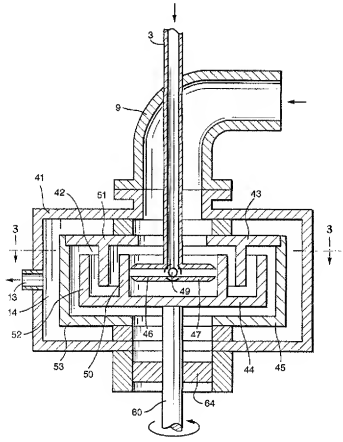


Fig. 2

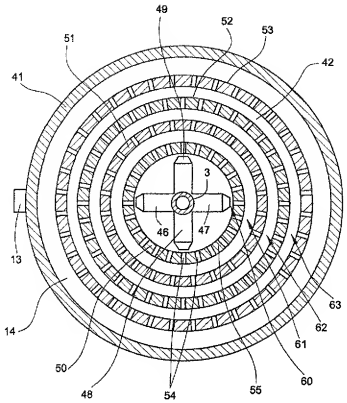


Fig. 3

With the foregoing summary information in mind, applicant now discusses the details. Applicant's claimed invention requires the following specific features and orientations that are not disclosed or suggested by Muller.

1. Applicants' claim 1 requires "a homogenization compartment in the form of a cylinder...wherein...said side walls are positioned along a **vertical** plane." See applicant's Figure 3 above and the vertical side walls designated as 8 and 8a. In contrast, the side walls of the Muller "compartment" are not vertical. In fact, Muller's sides designated as 41a and 41b in Muller's Figure 2 above are

horizontal and therefore teach away from the applicants' claimed invention that critically requires that applicants' "side walls are positioned along a **vertical** plane." Moreover, Muller's device would not be turned 90 degrees because then it would not function properly to expel its fibrets **horizontally** out from its rotating "star-shaped" nozzles 46, 47, 48, and 49 depicted in Figures 2 and 3 of Muller and described in column 9, lines 47-51 of Muller. Indeed, Muller specifically states that its "nozzles extend radially outward." Column 9, lines 50-51. Muller discloses no other configuration to make its specific type of fibrets. Thus, Muller does not disclose or suggest the claimed invention.

2. Applicants' claimed invention requires a "homogenization compartment in the form of a cylinder...wherein...the axis of symmetry of said cylinder is positioned **horizontally**." See reference number 4a in applicant's Figure 3 above. Muller does not disclose or suggest this feature. In fact, Muller teaches away from this critical feature of the claimed invention. In this regard, Muller's axis of symmetry of its cylinder is **vertical**. See reference number 40a in Muller's Figure 2 above. This contrary teaching of Muller cannot be ignored. Muller discloses no other configuration to make its specific type of fibrets. Thus, Muller does not disclose or suggest the claimed invention.

3. Applicants' claimed invention requires that "the rotor is installed so that it rotates about a **horizontal** axis which passes through said second side wall."

See reference number 4a in applicant's Figure 3 above. Muller does not disclose or suggest this claim feature. In fact, in Muller, the rotor moves around a **vertical** axis. See reference number 40a in Muller's Figure 2 above. Thus, Muller teaches away from the claimed invention.

4. Applicant's claimed invention requires that "the homogenization compartment exhibits a **top [horizontal] side on which said outlet is situated**." See reference number 5 in applicant's Figures 3 and 7 above. In contrast, Muller's outlet is on the **left vertical** side of its device. See reference number 13 in Muller's Figure 2 above. Again, this teaches away from the claimed invention.

For at least the foregoing reasons, the rejection fails to set forth a prima facie case of obviousness.

The Examiner's position appears to be that one skilled in the art would turn Muller's Figure 2 device 90 degrees and arrive at applicant's claim 1 invention. However, applicant submits that:

i) one skilled in the microparticles and nanoparticles art would not resort to Muller's "fibrets" invention - which was not successful, e.g., the Muller patent expired due to non-payment of maintenance fees, and

ii) Muller specifically teaches that its device must be used in the non-rotated position. No where does Muller teach or suggest that its device can be rotated 90 degrees. Indeed, the Muller device's rotation by 90 degrees would prevent the device from functioning properly to make the Muller "fibrets" that are supposed to be horizontally

> dispelled from Muller's particular "star-shaped" nozzles 46, 47, 48, and 49 in Figures 2 and 3.

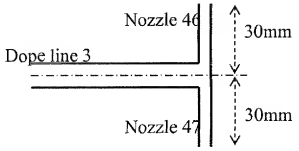
Only improper hindsight would lead a person of skill in the microparticles and nanoparticles art to resort to Muller and to rotate Muller's device 90 degrees, and, even when doing so, Muller's device for making fibrets would not work for its intended purpose (or even applicant's purpose) because of the positioning of Muller's inlets, their sizes, the rotor and stator configuration and required sprockets, and the specifically designed star-shaped nozzles that would no longer be horizontal. Such a rotated configuration of Muller would create inconsistent/problematic fibrets.

In particular, the following calculations show the technical impact that a rotation of the Muller device by 90 degrees would have. The following information shows that a rotated Muller device would not work properly for its intended purpose.

Muller generally aims at obtaining **fibret "fineness and homogeneity**." See, e.g., column 2, line 27; column 6, lines 34-35. To accomplish this goal, Muller requires a system ensuring "**identical conditions" "at all nozzles**." See, e.g., column 8, lines 13-15. Significantly, a rotation of the Muller device by 90 degrees would destroy this requirement and impair the fibret quality because "**identical conditions" "at all nozzles**" would not be met.

The following calculation is based on Example 1 in Muller (starting at column 10, line 51), with the following hypotheses to simplify the calculations:

- water is the fluid going through the "dope" delivery line into the dispersion facility;
- the calculation is made on a two-jet nozzle instead of a four-jet nozzle;
- the length of each nozzle is estimated to be 30mm, which is realistic in view of the Figures shown in Muller;



In Example 1, the dope is passed at ambient temperature at a mass flow rate of 3 kg/min. With the hypothesis of passing water through the system (just as a simplification, to limit the effect of viscosity in the feed line for the dope), the **flow rate** is 3 L/min, or **$5x10^{-5}$ m^3/s**.

Under a permanent regime, **the inlet flow rate**, via dope line 3, **equals the total outlet flow rate**, via nozzles 46 and 47. The outlet flow rate can be expressed as follows:

$$F_{out} = (v_{46} + v_{47}) \cdot S$$

with v_{46} and v_{47} being the velocity of the liquid in Nozzle 46 and Nozzle 47, respectively, and S being the outlet surface of each nozzle.

Example 1 of Müller specifies that the diameter of each nozzle is 5mm. Thus, the outlet surface of each nozzle is $\mathbf{S = S_{46} = S_{47} = (2.5x10^{-3})^2 . \pi = 1.96x10^{-5}\ m^2}$.

Thus, $F_{in} = F_{out} = 5x10^{-5}\ m^3/s = (v_{46} + v_{47})m/s . 1.96x10^{-5}\ m^2$

And $\mathbf{v_{46} + v_{47} = 2.55\ m/s}$ **(Equation 1).**

For an incompressible flow as in the dope line, Bernoulli's principle is as follows:

$$\frac{v^2}{2} + gz + \frac{p}{\rho} = \text{constant}$$

where:

v is the fluid flow speed at a point on a streamline,
g is the acceleration due to gravity,
z is the elevation of the point above a reference plane, with the positive z-direction pointing upward — so in the direction opposite to the gravitational acceleration,
p is the pressure at the point, and
ρ is the density of the fluid at all points in the fluid.

$$\frac{v_{46}^2}{2} + g z_{46} + \frac{P_{46}}{\rho} = \frac{v_{47}^2}{2} + g z_{47} + \frac{P_{47}}{\rho}$$

with $P_{46} = P_{47}$ since the diameters of nozzles 46 and 47 are equal

$$(v_{46}^2 - v_{47}^2) / 2 = - g (z_{47} - z_{46})$$

$$v_{46}^2 - v_{47}^2 = - 2g \Delta z \quad \textbf{(Equation 2)}$$

From Equation 1, we know that $v_{47} = 2.55 - v_{46}$

Thus, Equation 2 becomes

$$2.55^2 - 2 (2.55 \cdot v_{47}) + v_{47}^2 - v_{47}^2 = - 2g \Delta z$$

$$v_{47} = \frac{2.55 + 2g \Delta z}{5.1}$$

$$v_{47} = 1.51 \text{ m/s.}$$

And $v_{46} = 2.55 - v_{47} = 1.04$ m/s.

From these velocity values, we then readily conclude that

- the outlet flow rate from nozzle 47 is $F_{47} = v_{47} \cdot S_{47} =$ **1.78 L/min**
- the outlet flow rate from nozzle 46 is $F_{46} = v_{46} \cdot S_{46} =$ **1.22 L/min**

Thus, rotating the Müller device by 90 degrees would **defeat** the purpose of ensuring **identical conditions** at each nozzle, and would not result in the required fibret fineness and homogeneity – because, at a minimum, the flow rates for feeding the dope into the dispersing facility would differ from one nozzle to the other nozzle, at least partly due to the gravity effect.

For at least the foregoing reasons, Muller's device must be used in the fashion shown in Muller's patent. When properly reading Muller, applicant's

claimed design is counter-intuitive – which is further evidence of non-obviousness.

Finally, with respect to applicant's dependent claim 4, the claimed first inlet "perforations" are quite different than Muller's specifically designed star-shaped nozzles 46, 47, 48, and 49 that extend "radially outward." See Muller at column 9, lines 50-51. No one skilled in the art would view the term "perforations" to be the same as or an obvious variant of Muller's specifically designed star-shaped nozzles that extend "radially outward." Consequently, Muller does not disclose or suggest the applicant's claim 4 invention.

For at least the foregoing reasons, applicant requests the reversal of the claim rejections.

CONCLUSION

Applicant respectfully requests the Board to reverse the final rejection and pass the subject application to issue.

Respectfully submitted,

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(VIII) CLAIMS APPENDIX

1. (rejected) A device for the continuous manufacture of microparticles or nanoparticles from at least one aqueous phase and one organic phase comprising:

a homogenization compartment in the form of a cylinder which is defined by a tubular wall forming the casing of said cylinder and by a first side wall and a second side wall which are positioned at each end of said tubular wall;

the device additionally comprising a first inlet and a second inlet which pass through said first side wall and which are appropriate for respectively delivering an organic phase and an aqueous phase to the homogenization compartment and an outlet appropriate for extracting a particle suspension from the homogenization compartment;

the homogenization compartment including a mixing system comprising a rotor/stator combination, wherein

a) said side walls are positioned along a vertical plane,

b) the axis of symmetry of said cylinder is positioned horizontally,

c) the rotor is installed so that it rotates about a horizontal axis which passes through said second side wall,

d) said first inlet is a hollow tube positioned in the extension of the axis of the rotor and comprises a tip situated inside the rotor and inside the stator, and

e) the homogenization compartment exhibits a top side on which said outlet is situated.

2. (rejected) The device as claimed in claim 1, wherein the rotor and the stator are cylindrical in shape.

3. (cancelled)

4. (rejected) The device as claimed in claim 1, wherein the first inlet comprises perforations.

5. (rejected) The device as claimed in claim 4, wherein the number of perforations is from 1 to 20.

6. (rejected) The device as claimed in claim 4, wherein the perforations have a diameter from 0.01 mm to 1 mm.

7. (rejected) The device as claimed in claim 1, wherein the dimensions of the rotor/stator combination are such that the mixing system occupies 4% to 40% of the volume of the homogenization compartment.

8-12. (cancelled)

13. (rejected) The device as claimed in claim 5, wherein the rotor and the stator comprise a row of teeth and that the spacing between the teeth is from 1 to 4 mm.

(IX) EVIDENCE APPENDIX

Not Applicable.

(X) RELATED PROCEEDINGS APPENDIX

Not Applicable.